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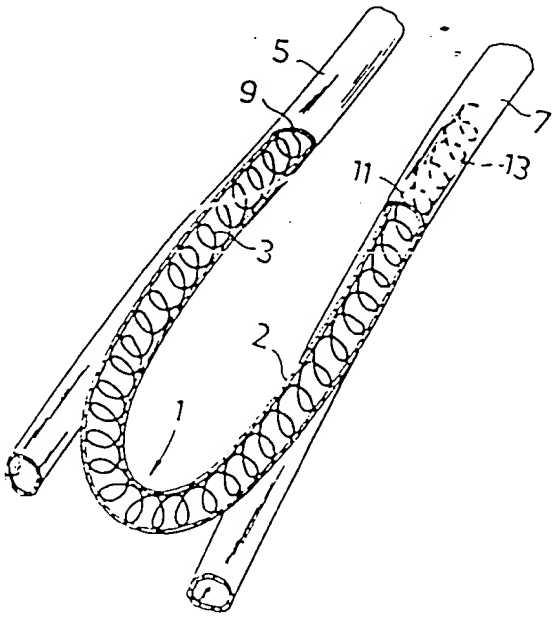
(54) Title: BLOOD VESSEL PROSTHESIS

(57) Abstract

Blood vessel prosthesis for use as a by-pass between blood vessel (5, 7), particularly between artery and vein, comprising a tubular element (2) of a tissue-compatible material. The blood vessel prosthesis is characterized by an interior elastically resilient support member (3) which at least at one end (11) of said element (2) extends outside said end for a distance (13); and a process for implanting the blood vessel prosthesis.



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TITLE OF THE INVENTION:
Blood vessel prosthesis.

The present invention relates to a blood vessel prosthesis of a new type, particularly for use as a coupling piece or by-pass between blood vessels, in particular between vein and artery.

In the medicinal technique it is a relatively frequent requirement for the drainage of blood for analysis-experimental or purification purposes to be able to introduce a blood vessel prosthesis, so-called by-pass, between blood vessels. This by pass which may be implanted for a long time is then used as a drainage site for blood for the intended purpose. Particularly in so-called haemodialysis which is carried out on patients having disturbances in the kidney function it is common to use implanted blood vessel prostheses or by-passes which are used at regular intervals, up to several times per week, in connection with the purification of the blood in a so-called artificial kidney.

Known blood vessel prostheses or by-passes used for example in connection with performing haemodialysis are, however, subject to serious inconveniencies. As a blood vessel prosthesis there is usually used a so-called heterograft, i.e. a piece of blood vessel taken from an animal, for example of bovine, ovine or procine origin. Such heterografts treated in a particular way are called xenografts and consist of chemically or physically treated blood vessels from animals for the purpose of enduring long time implantation and for the purpose of constituting a tissue-compatible material. Such by-pass is introduced by surgical operation with the one end thereof in an artery and the other end in a vein, for example in the arm of a patient, and it connects in this

manner said two blood vessels enabling intermittent drainage of blood, purification of the drained blood and returning same to the blood system of the patient.

In connection with the use of this type of graft for coupling an artery and a vein together there are, however, practical problems, among which the following may be mentioned.

In connection with the drainage of blood the by-pass where it is implanted by operation under the skin of the patient is punctured with a cannula. After repeated drainage the by-pass loses its elasticity, and when after finished blood treatment the cannula is withdrawn it is required in the usual manner that pressure is applied to the site of drainage for the purpose of obtaining coagulation of the blood in the same way as in the conventional drainage of blood for blood analysis. When the material of the by-pass has lost its elasticity this is reflected by the fact that when after having reached the blood coagulation by applying external pressure on the by-pass the pressure on the by-pass or blood vessel prosthesis is then released the latter does not revert to its normal expanded position but remains in a compressed position thereby disturbing the blood circulation.

Another problem in using this type of blood vessel prosthesis may consist in influence by the by-passed blood flow on the vein tissue in connection with the area where one end of the prosthesis has been implanted by operation. Experience inter alia shows that this results in so-called stenosis formed in the vein some centimeters inside the site of connection of the blood vessel prosthesis.

The present invention has for its purpose to provide a blood vessel prosthesis wherein the above-indicated problems are eliminated or at any rate essentially reduced.

Another purpose of the invention is to provide a process for the application of such blood vessel prostheses operating as a by-pass, particularly for connecting an artery to a vein.

In connection with the creation of the present invention it has been found possible to provide a blood vessel prosthesis comprising a tubular element of a tissue-compatible material, which blood vessel prosthesis constitutes essential advantages compared to the prior art as indicated above. The blood vessel prosthesis according to the invention is provided with an interior elastically resilient support member which at least at one end of the element extends outside said end. When applying the invention to permanent or long lasting connection of an artery to a vein the said end of the tubular element is connected to the vein and the outwardly extending support member thus extends into the vein for the purpose of maintaining the vein from the inside in an expanded position so as not to disturb the blood circulation.

The tubular element may be made of any tissue-compatible material of native or synthetic nature. Thus, there may be used in said elements different types of traditional graft materials as used in for example heterografts, particularly of bovine, ovine or porcine origin. According to the present invention it is preferred to use in the tubular element such materials which are present in so-called xenografts, which are chemically or physically particularly prepared heterografts. Alternatively, synthetic tissue compatible materials may be used, such as polyethylene terephthalate, polytetrafluoro ethylene, polyethylene, polypropylene etc. However, in accordance with this invention it is particularly preferred to use a non-human, biological material of the heterograft type.

The support member arranged within the tubular element can be designed in many ways. It may for example consist of a helix-shaped spiral spring which engages the interior wall of the element with an adjusted pressure. As a material in this spiral spring there may be used a tissue compatible metal, for example stainless steel, or a plastic material of sufficient rigidity. Further details concerning such spiral springs are clear from Swedish patent application 8202740-0.

Alternatively, there may be used as a support member a flexible tubular body which is composed of several individual rigid but flexible thread elements, each of which extends in helix configuration with the center line of the body as a common axis. A number of elements have the same direction of winding but are axially displaced relative to each other. The said number of elements having the same direction of winding meet and cross a number of thread elements which also are axially displaced relative to each other but have the opposite direction of winding. Such tubular body can be expanded by axial shortage of body or may obtain reduced diameter by axial elongation of the body.

The diameter of the blood vessel prosthesis may vary within relatively wide limits depending on where it is applied but the most frequent dimension may lie between about 3 and 10 mm. The part of the support member extending outside the tubular element has suitably a length of up to about 20 times the inner diameter of the tubular element, particularly about 3-12 times the said diameter to give the desired function. In this manner there is obtained by means of the extending end of the support member a satisfactory supporting function inside the surrounding blood vessel, particularly when the vessel consists of a vein where, as is known, the blood

pressure is low and even in some cases may be negative relative to the atmospheric pressure.

By using the blood vessel prosthesis according to the present invention the problems introductorily mentioned are eliminated in a simple and efficient manner. Thus, the prosthesis for the whole period of implantation maintains a satisfactory elasticity so that blood drainage can take place without problems. A further advantage when using a spiral spring or tubular member composed of oppositely directed spiral elements resides is the fact that introducing a cannula in the prosthesis results in widening of the spring material which then after the removal of the cannula and the return of the support member to normal position results in contraction of the opening of the prosthesis caused by the cannula so as to provide for almost autosealing. Thanks to the extending part of the support member also the risk of the formation of stenosis in connection with the application site of a vein will be avoided.

The present invention will in the following be further described by a non-limiting example in connection with the appended drawing. In the drawing there is shown: a diagrammatic view of the blood vessel prosthesis according to the present invention applied for long lasting implantation for carrying out haemodialyses at regular intervals.

In the drawing there is shown diagrammatically a blood vessel prosthesis generally indicated 1 according to the invention coupled between an artery 5 and a vein 7. The by-pass or blood vessel prosthesis 1 contains as a support member a helix-shaped spiral spring 3 which extends from the site 9 of application of the artery through the tubular element 2 up to and beyond connecting site 11 of the vein 7 a distance 13.

The tubular element 2 is preferably constituted by

a so-called xenograft, for example of bovine origin, i.e. a heterograft treated chemically and/or physically in a suitable manner. Spiral spring 3 can be constituted by a medicinally acceptable stainless steel.

The manner of applying or implanting the blood vessel prosthesis for connecting artery 5 to vein 7 may for example be briefly as follows.

As a first step the vein 7 of the patient is opened by surgical incision, whereafter the tubular element 2, for example the xenograft, is attached to the vein by sewing in a conventional manner. Then spiral spring 3 is inserted from outside into the tubular element 1, which is done by contracting spiral spring 3 in some suitable way, for example by rotating the ends relative to each other, and spiral spring 3 is then positioned in the position shown in the drawing and is subjected to expansion for fixation in this position with a pressure adapted for the purpose. The end extending towards vein 7 extends outside the tubular element 1 a suitable distance 13 which, when applied to haemodialysis may be about 3-4 cm.

After applying the spiral spring 3 in the tubular element 1 the opposite end of spring 3 is severed at the location of the other end of the tubular element. Then the skin of the patient is opened and the blood vessel prosthesis is inserted below the skin and attached to the opened artery 5 by sewing. At this end 9 of the blood vessel prosthesis 1 no extending end of spiral spring 3 will be required since overpressure exists in the artery.

After applying the blood vessel prosthesis the prosthesis may now be easily localized and can be easily punctured for drainage of blood.

In regard to details concerning the construction of spiral spring 3 and its application reference is

made to the above-mentioned Swedish patent application 8202740-0.

Among several useful support members another device may be mentioned. In this device the mantle surface of the body consists of a number of individual thread elements. Of these thread elements one set of elements extend in helix configuration axially displaced relative to each other with the center line of the body as a common axis. The other set of element extends in helix configuration in the opposite direction of winding, the thread elements extending in opposite directions crossing each other to form a cylindrical plaited configuration.

The diameter of a tubular body built up in this manner can be varied by axial displacement of the ends of the body in relation to each other in the direction of the center line. The tubular body can be expanded in several ways and it is preferred that the body inherently has the ability of taking expanded position by itself in its released state. This can be provided by using the tension of the material of the body.

In other respects the function of the support member now described is the same as has been described in connection with the drawing.

It should be observed that the invention is not limited to the embodiments and applications described above. Thus, the device of the invention can be used at all times when it is desired by using a so-called by-pass to connect two blood vessels to each other for the purpose of draining blood for the taking of samples, analyses, dialyses etc. Nor is the process for attaching the blood vessel prosthesis limited to that described above. Thus, it is well conceivable that the tubular element is provided in advance with an interior support member, for example a spiral spring, and one must see

to it that at least one end of the element of the support member extends outside the end of said element for a certain distance. The tubular element provided in advance with a support member is then attached by sewing at the end where the support member extends to the exterior to a vein, whereas the other end of the element is attached to an artery.

In addition to the advantages provided by the invention as described above the further advantage will be obtained that the blood vessel prosthesis after being positioned subcutaneously, for example for use in haemodialysis, will be better attached without rotation or folding which is the case with previously used blood vessel prostheses. Thanks to the interior support member the blood vessel prosthesis obtains an elasticity which makes it safe in operation and easy to use.

PATENT CLAIMS:

1. Blood vessel prosthesis for use as a by-pass between blood vessels (5, 7), particularly between artery and vein, comprising a tubular element (2) of a tissue-compatible material, characterized by an interior elastically resilient support member (3) which at least at one end (11) of said element (2) extends outside said end for a distance (13).

2. Blood vessel prosthesis according to claim 1, characterized in that said element (2) consists of a so-called heterograft, particularly a xenograft, of bovine, ovine or procine origin.

3. Blood vessel prosthesis according to claim 1, characterized in that said element (2) consists of a synthetic material.

4. Blood vessel prosthesis according to any preceding claim, characterized thereby that said support member consists of a helix-shaped spiral spring (3) which engages the interior wall of the element (2) with an adjusted pressure.

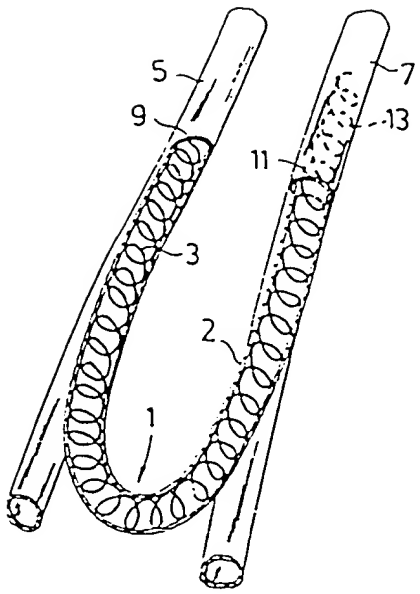
5. Blood vessel prosthesis according to any of claims 1-3, characterized in that said support member consists of a tubular body which is composed of several individual rigid but flexible thread elements, each of which extends in helix configuration with the center line of the body as a common axis, a number of elements having the same direction of winding but being axially displaced relative to each other crossing a number of thread elements which also are axially displaced relative to each other but have the opposite direction of winding.

6. Blood vessel prosthesis according to any preceding claim, characterized in that said distance

(13) is of a length of up to about 20, particularly about 3-12 times the diameter of the tubular element (2).

7. A process for implanting a blood vessel prosthesis functioning as a by-pass between an artery (5) and a vein (7), characterized by connecting a tubular element (2) at one end thereof to the vein (7), then inserting into the tubular element (2) a supporting member (3) acting from the inside, said supporting member at said one end extending a distance inside the vein (7) to support same, and then connecting the other end of the tubular element (2) to the artery (5).

8. Modification of the process according to claim 7, characterized in that the support member (3) is introduced into the tubular element (2) before its attachment to the vein (7).



INTERNATIONAL SEARCH REPORT

International Application No PCT/SE84/00025

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)

According to International Patent Classification (IPC) or to both National Classification and IPC

A 61 F 1/00 // A 61 B 17/00

II. FIELDS SEARCHED

Minimum Documentation Searched	
Classification System	Classification Symbols
IPC 3	A 61 B 17/00,04,12; A 61 F 1/00; A 61 L 17/00
US Cl	3: 1.4; 128: 325, 326, 334

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched

SE, NO, DK, FI classes as above

III. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No.
A	SE, B, 397 769 (S E BERGENTZ ET AL) 21 November 1977, see fig 8	1-8
A	SE, B, 424 401 (S BOWALD) 19 July 1982	1-3,5
P	SE, A, 8105510-5 (H I WALLSTEIN ET AL) 17 March 1983	1-8
A	DE, A, 2 152 142 (M KRAJICZEK ET AL) 25 May 1972	2-8
A	US, A, 3 562 820 (B BRAUN) 16 February 1971	1-8
A	US, A, 4 130 904 (R L WHALEN) 26 December 1978	1-8
A	US, A, 4 300 244 (J C BOKROS) 17 November 1981	1-8

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IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
1984-05-09	1984-05-15
International Searching Authority	Signature of Authorized Officer
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Form PCT/ISA/210 (second sheet) (October 1981)

K.L.